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## IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicants: Judith Fitzpatrick, Regina B. Lenda, and Christopher L. Jones

Serial No.: 09/526,582 Art Unit: Not Yet Assigned

Filed: March 16, 2000 Examiner: Not Yet Assigned

For: *METHOD AND DEVICE FOR DETECTION OF APO A, APO B AND THE RATIO THEREOF IN SALIVA*Assistant Commissioner for Patents  
Washington, D.C. 20231**INFORMATION DISCLOSURE STATEMENT**

Sir:

Pursuant to 37 C.F.R. §1.56 and 37 C.F.R. §1.97, Applicants submit an Information Disclosure Statement, including ten (10) pages of Form PTO-1449 and a copy of each document cited therein.

This Information Disclosure Statement is being filed under 37 C.F.R. § 1.97(b) prior to a first Office Action on the merits. It is believed that no fee is required with this submission. However, should a fee be required, the Commissioner is hereby authorized to charge any required fees to Deposit Account No. 01-2507.

**U.S. Patents**

<u>Number</u>	<u>Issue Date</u>	<u>Patentee</u>	<u>Class/Subclass</u>
5,451,504	09-19-1995	Fitzpatrick, et al.	435/7.2
5,500,375	03-19-1996	Lee-Own, et al.	436/514
5,710,009	01-20-1998	Fitzpatrick, et al.	435/7.9

**Foreign Patent Documents**

<u>Number</u>	<u>Publication Date</u>	<u>Patentee</u>	<u>Country</u>
WO 93/18067	09-16-1993	Abbott Laboratories	PCT
WO 96/00903	01-11-1996	Oklahoma Medical Research Foundation	PCT

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WO 98/06827

02-19-1998

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**Remarks**

This statement should not be interpreted as a representation that an exhaustive search has been conducted or that no better art exists. Moreover, Applicants invite the Examiner to make an independent evaluation of the cited art to determine its relevance to the subject matter of the present application. Applicants are of the opinion that their claims patentably distinguish over the art referred to herein, either alone or in combination.

Respectfully submitted,

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Patrete L. Pabst  
Reg. No. 31,284

Dated: June 26, 2000

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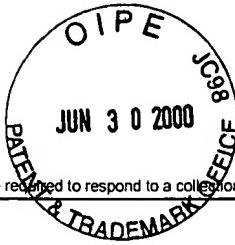
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Julie A. Tennyson  
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		Application Number	09/526,582
		Filing Date	March 16, 2000
		First Named Inventor	Judith Fitzpatrick
		Group Art Unit	
		Examiner Name	
		Attorney Docket Number	SRX 110
Sheet	1	of	10

U.S. PATENT DOCUMENTS

## **FOREIGN PATENT DOCUMENTS**

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Filing Date	March 16, 2000		
First Named Inventor	Judith Fitzpatrick		
Group Art Unit			
Examiner Name			
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OTHER ART - NON PATENT LITERATURE DOCUMENTS		
Examiner's Initials*	Cite No. <sup>1</sup>	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published
		"Report of the Expert Panel on Blood Cholesterol Levels in Children and Adolescents," <i>Pediatrics</i> 89:525-584 (1992).
		"Report of the National Cholesterol Education Program Expert Panel on Detection, Evaluation, and Treatment of High Blood Cholesterol in Adults," <i>Arch. Intern. Med.</i> 148:36-69 (1988).
		"Report of the Working Group on Atherosclerosis of the National Heart and Lung and Blood Institute," 2 (Washington, D.C.: Government Printing Office, 1981) DHEW Publication No. (NIH) 82-2035.
		"The Lipid Research Clinics Coronary Primary Prevention Trial Results: II", <i>JAMA</i> , 251:365-374 (1984).
	→	ALAUPOVIC, "David Rubinstein Memorial Lecture: The Biochemical and Clinical Significance of the Interrelationship Between Very Low Density and High Density Lipoproteins," <i>Can. J. Biochem.</i> 59:565-579 (1981).
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		ASSMANN, et al., "The Hypertriglyceridemias: Risk and Management," <i>Am. J. Cardiol.</i> 68(3):1A-4A (1991).

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Sheet	3	of	10
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OTHER ART -- NON PATENT LITERATURE DOCUMENTS		
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		ATMEH, et al., "Subpopulations of Apolipoprotein A-I in Human High-Density Lipoproteins, Their Metabolic Properties and Response to Drug Therapy," <i>Biochim. Biophys. Acta.</i> 751:175-188 (1983).
		AVOGARDO, et al., "Are Apolipoproteins Better Discriminators than Lipids for Atherosclerosis?" <i>Lancet</i> 1:901-903 (1979).
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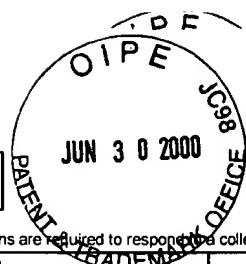
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Application Number	09/526,582
Filing Date	March 16, 2000
First Named Inventor	Judith Fitzpatrick
Group Art Unit	
Examiner Name	

Sheet	4	of	10	Attorney Docket Number	SRX 110
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		CURRY, et al., "Quantitative Determination of Human Apolipoprotein C-III by Electroimmunoassay," <i>Biochim. Biophys. Acta.</i> 617:503-513 (1980).	
		CWIRLA, et al., "Peptides on phage:A vast library of peptides for identifying ligands," <i>Proc. Natl. Acad. Sci. USA</i> 87:6378-6382 (1990).	
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		GODING, "Monoclonal Antibodies: Principles and Practice," pp 56-97, Academic Press, Inc.:New York (1983).	

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Sheet	5	of	10	Attorney Docket Number	SRX 110
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		GOHLKE, "Influence of the LDS-/HDL-Cholesterol Ratio on Progression and Regression of Atherosclerotic Lesions. A Review of Controlled Angiographic Intervention Trials," <i>Wien Klin. Wochenschr.</i> 104(11):309-313 (1992).	
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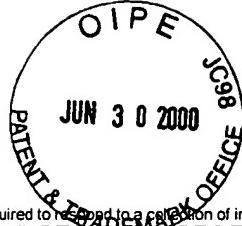
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		KWITEROVICH, et al., "Comparison of the Plasma Levels of Apolipoprotein B and A-1, and Other Risk Factors in Men and Women with Premature Coronary Artery Disease," <i>Am. J. Cardiol.</i> 69:1015-1021 (1992).	
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		LOPES-VIRELLA, et al., "Cholesterol Determination in High-Density Lipoproteins Separated by Three Different Methods," <i>Clin. Chem.</i> 23:(5):882-884 (1977).	
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		MANDEL & EISENSTEIN, "Lipids in human salivary secretions and salivary calculus," <i>Arch. Oral Biol.</i> 14(2):231-3 (1969).	

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<b>INFORMATION DISCLOSURE STATEMENT BY APPLICANT</b>  (use as many sheets as necessary)		Application Number	09/526,582
Filing Date	March 16, 2000		
First Named Inventor	Judith Fitzpatrick		
Group Art Unit			
Examiner Name			
Sheet 7 of 10	Attorney Docket Number	SRX 110	

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		MARCEL, et al., "Expression of human apolipoprotein A-I epitopes in high density lipoproteins and in serum," <i>J. Lipid Res.</i> 28(7):768-77 (1987).
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		OLOFSSON, et al., "Isolation and Partial Characterization of a Polypeptide Belonging to Apolipoprotein B from Low-Density Lipoproteins of Human Plasma," <i>Biochemistry</i> 19:1059-1064 (1980).
		ORTOLÁ, et al., "Biological Variation Data Applied to the Selection of Serum Lipid Ratios used as Risk Markers of Coronary heart Disease," <i>Clin. Chem.</i> 38(1):56-59 (1992).
		OSBORNE & BREWER, "The plasma lipoproteins," <i>Adv. Protein Chem.</i> 31:253-337 (1977).

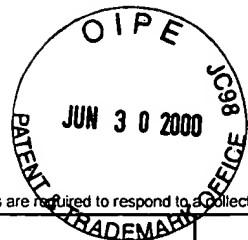
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Application Number	09/526,582				
Filing Date	March 16, 2000				
First Named Inventor	Judith Fitzpatrick				
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Sheet	8	of	10	Attorney Docket Number	SRX 110

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		PARHAM, "Handbook of Experimental Immunology, Vol. 1: Immunochemistry," (Weir, D.M., Editor), Blackwell Scientific Publications:Oxford, 1986.	
		PARMLEY, et al., "Filamentous Fusion Phage Cloning Vectors for the Study of Epitopes and Design of Vaccines," <i>Adv. Exp. Med. Biol.</i> 251:215-218 (1989).	
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		SLOMIANY, et al, "Association of lipids with proteins and glycoproteins in human saliva," <i>J. Dent. Res.</i> 62(1):24-7 (1983).	
		SLOMIANY, et al, "Lipid composition of human parotid and submandibular saliva from caries-resistant and caries-susceptible adults," <i>Arch. Oral Biol.</i> 27(10):803-8 (1982).	
		SMITH, et al., "The plasma lipoproteins: structure and metabolism," <i>Annu. Rev. Biochem.</i> 47:751-7 (1978).	
		SNIDERMAN, et al., "Association of Coronary Atherosclerosis with Hyperapobetalipoproteinemia [Increased Protein but Normal Cholesterol Levels in Human Plasma Low Density ( $\beta$ ) Lipoproteins], <i>Proc. Natl. Acad. Sci. USA</i> 77(1):604-608 (1980).	

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Application Number 09/526,582

Filing Date March 16, 2000  
First Named Inventor Judith Fitzpatrick  
Group Art Unit  
Examiner Name

Sheet 9 of 10 Attorney Docket Number SRX 110

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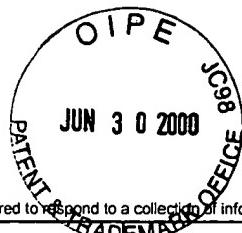
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First Named Inventor	Judith Fitzpatrick
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Examiner's Signature	Date Considered
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